Journal of Cardiovascular Magnetic Resonance®, 3(3), 171–182 (2001)

INVITED PAPER

Magnetic Resonance Imaging Safety: Implications for Cardiovascular Patients

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ABSTRACT

The potential bioeffects associated with magnetic resonance (MR) procedures result from exposure to the static, gradient, and radiofrequency electromagnetic fields. Each electromagnetic field represents a possible health risk at sufficiently high levels of exposure. The presence of certain biomedical implants and devices may pose hazards for patients undergoing MR procedures. Additionally, other safety issues must be considered for patients in the MR environment. This review article discusses the bioeffects of MR exposures and provides an overview of safety considerations, with an emphasis on information pertinent to cardiovascular patients.
Key Words: *Biomedical implants; Cardiac; Magnetic resonance (MR); Safety*

INTRODUCTION

The clinical magnetic resonance (MR) procedure exposes the patient to electromagnetic radiation, which may present a potential health risk if excessive levels are used (1–50). The presence of certain biomedical implants and devices may represent hazards for patients undergoing MR procedures (51). Additionally, other safety issues must be considered for patients in the MR environment (1,51–90).

As MR technology continues to evolve, MR systems using higher static magnetic fields, higher and faster gradient fields, and stronger radiofrequency (RF) fields are becoming increasingly common. The past decade has also witnessed an exponential increase in the employment of MR-guided surgery, posing additional safety issues.

Due to the rapid advances in MR technology, the potential exists for insufficient safety awareness among clinicians using this diagnostic modality. The purpose of this review article is to provide an updated presentation of the bioeffects of MR exposures and a discussion of

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other safety considerations, with an emphasis on information pertaining to the cardiovascular patient.

BIOEFFECTS OF STATIC MAGNETIC FIELDS

The strengths of static magnetic fields used in clinical and research MR systems range from 0.064 T to 8.0 T. Exposing patients to the static magnetic field of an MR system places them at potential risk for several bioeffects, including changes in cardiovascular dynamics, tissue temperatures, and nerve bioelectric activity.

Cardiovascular Effects

A direct cardiac effect may be observed as a result of blood, a conductive fluid, flowing through the static magnetic field and generating a biopotential (1,75). The induced biopotential is manifested by an augmentation in T-wave amplitude, which is directly proportional to the intensity of the static magnetic field (2–4). This biopotential can falsely trigger the RF excitation during cardiac gated MR studies. Alternate lead positions can be used to diminish the static magnetic field–induced electrocardiographic (ECG) changes to facilitate cardiac gated studies (5).

Because there are no other circulatory alterations that coincide with the ECG changes, no short-term biologic risks are believed to be associated with the cardiac effects that occur in conjunction with exposure to static magnetic field strengths up to 2.0 T (1,75). However, because an elevation in T-wave amplitude may be indicative of a cardiac abnormality, it may be necessary to monitor the ECG in a high-risk patient immediately before and after the MR procedure to identify any possible alterations that could have occurred during the examination (2–4).

Temperature Effects

Reports have indicated that static magnetic fields either increase or both increase and decrease temperature, depending on the orientation of the organism in reference to the static magnetic field (6,7). However, none of these studies proposed a plausible mechanism for these changes. Other investigations conducted specifically to determine if exposure to a 1.5-T static magnetic field alters skin and body temperatures in humans reported no statistically significant changes in temperature (8–10). Notably, this research was performed using a special fluoroptic thermometry system known to be unperturbed by high-intensity static magnetic fields. Therefore, skin and body temperatures are believed to be unaffected by exposure to static magnetic fields up to 1.5 T (8–10).

Nervous System Effects

Several studies have failed to identify any effects with respect to cognition, acute or chronic behavior changes, or memory alterations (11–15) caused by exposure to MR procedures. Exposure of human subjects to static magnetic fields of 4.0 T has resulted in sensations of nausea, vertigo, and a metallic taste (16,17). These sensations are thought to result from an alteration in nerve function associated with the exposure to, or movement through, the high-intensity static magnetic field. Presently it is believed that exposure to static magnetic fields of up to 2.0 T does not significantly influence bioelectric properties of neurons in human subjects.

BIOEFFECTS OF GRADIENT MAGNETIC FIELDS

According to Faraday's law of induction, gradient magnetic fields can induce electric fields and currents in conductive media, including biological tissues (18). The bioeffects of gradient magnetic fields can be caused by possible thermal effects or by direct neuromuscular stimulation resulting from induced currents (athermal effects). Thermal effects due to switched gradients used in MR imaging (MRI) are negligible and not believed to be clinically significant (18–20).

The athermal effects (i.e., those not associated with a temperature increase) of induced currents include stimulation of nerve or muscle cells, induction of ventricular fibrillation, increased brain mannitol space, generation of epileptogenic potential, and elicitation of magnetophosphenes (20–26).

An MRI guidance update, issued by the U.S. Food and Drug Administration (FDA) in 1995, set painful peripheral nerve stimulation as the target threshold to avoid (as opposed to simple twitching). The report indicated that mild stimulation is not considered harmful, and the examination does not need to be terminated if the patient experiences mild peripheral stimulation (27).

With respect to cardiac stimulation, studies have indicated that cardiac thresholds are significantly greater than those necessary to cause neuromuscular excitation (21, 24–26,28–31). Seizure induction thresholds seem to be even higher than cardiac thresholds.

Recently, the MR industry has seen a marked advance in the capabilities of the gradient magnetic field subsystems of the MR systems, such as increased peak gradient amplitudes and decreased rise times to maximum amplitude. With the introduction of echo planar imaging technology into the clinical MR setting, there is increased potential for exposing patients to higher levels of induced voltages. Several investigators have reported what is believed to represent direct peripheral nerve stimulation in the form of involuntary, uncontrolled, skeletal musculature contractions and/or twitching in human subjects induced from echo planar imaging sequences (24–26,29, 31). The threshold for these gradient magnetic field–induced bioeffects has been observed at 60 T/sec or beyond. The positioning of the subject also seems to play a role in the severity of the response to stimulation (31).

BIOEFFECTS OF RF ELECTROMAGNETIC FIELDS

RF radiation is capable of generating heat in tissues due to resistive losses that can potentially result in thermal-related bioeffects (18,20,23,33–39). Exposure to RF radiation may also cause athermal field-specific alterations in biological systems that are produced without any significant increases in temperature (40–43). Athermal bioeffects of RF radiation are controversial because of assertions concerning the role of electromagnetic fields in causing cancer and developmental abnormalities (40–44). A report from the U.S. Environmental Protection Agency indicated that the existing evidence on this issue is sufficient to demonstrate a relationship between chronic exposures to low-level electromagnetic fields and cancer (44).

Investigators have typically quantified the exposure to RF radiation by means of determining the specific absorption rate (SAR). The SAR is the mass normalized rate at which RF power is coupled to biological tissue and is commonly indicated in units of watts per kilogram (W/kg). An extensive research study, performed with volunteer subjects exposed to whole body–averaged SAR of 6.0 W/kg, reported statistically significant changes in skin temperature. However, the temperature changes were within FDA guidelines (45,46). These data indicate that MRI performed at 6.0 W/kg can be tolerated by individuals with normal thermoregulatory function (46).

Notably, individuals with compromised thermoregulatory effectors may not be capable of efficiently dissipating a heat load, leading to an accumulation of heat along with an elevation in local and/or overall tissue temperature. Certain underlying health conditions may affect an individual's ability to tolerate a thermal challenge, including cardiovascular disease, hypertension, diabetes, fever, old age, and obesity (91–96). Various medications (diuretics, β-blockers, calcium channel blockers, amphetamines, muscle relaxants, sedatives) can also alter the thermoregulatory responses to a heat load (1). Several types of medications have a synergistic effect with respect to tissue heating if the heating is caused by exposure to RF radiation (97,98). Further studies are necessary to ascertain the thermal effect of RF radiation on patients with the above-mentioned specifications.

MR PROCEDURES AND ACOUSTIC NOISE

The acoustic noise produced during MR procedures represents a potential risk to patients. The gradient magnetic field is the primary source of acoustic noise associated with MR procedures (1,47–49,75). Studies evaluating worst-case pulse sequences showed that fast gradient echo pulse sequences produced the greatest noise during MRI (49). However, in all instances the acoustic noise levels did not exceed levels permissible by the Occupational Safety and Health Administration.

The safest and least expensive noise reduction technique involves the use of earplugs. The use of earplugs has been shown successfully to avoid the temporary hearing loss associated with MR procedures. Additionally, a significant decrease in acoustic noise (as much as 50–70%) has been achieved with the use of an active noise cancellation technique (48).

MR PROCEDURES AND PREGNANCY

With regards to the pregnant patient, there does not seem to be sufficient evidence supporting or refuting the overall safety of the electromagnetic fields used for MR procedures. In cases where the referring physician and the radiologist can defend that the findings of the MR examination have the potential to alter the care of the mother or fetus, the MR procedure may be performed with informed consent, regardless of trimester (1,75).

According to the MR safety committee of the Society for Magnetic Resonance Imaging, MR studies are indicated for use in pregnant women if other non-ionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would

otherwise require exposure to ionizing radiation (1,75). It is recommended to inform the pregnant patient that, to date, there is no indication that the use of clinical MR during pregnancy has produced deleterious effects. However, the safety of MR during pregnancy has not been proven (1,45,75).

SCREENING FOR PATIENTS WITH METALLIC FOREIGN BODIES

All patients with a history of being injured by a metallic foreign body such as a bullet or shrapnel should be thoroughly evaluated before admission to the area of the MR system (1,16,23–26,30–35,40–42,51,75). The relative risk of scanning these patients depends on the ferromagnetic properties of the object, the geometry and dimensions of the object, and the strength of the static and gradient magnetic fields of the scanner. Additionally, the potential for injury is related to the force with which the object is fixed within the tissue and whether it is positioned within or adjacent to a potentially hazardous location of the body, such as a vital neural, vascular, or soft-tissue structure (1,23,35,51,75).

Patients should initially be given a questionnaire to assess their relative risk of having metallic foreign bodies. Plain-film radiography is a sensitive and relatively inexpensive technique that can be used for identifying or excluding a metallic foreign body among patients with a significant risk for bearing such objects (1,23,50,51, 75,99,100).

For example, a patient with a high suspicion of having an intraocular metallic foreign body (e.g., a metal worker exposed to metallic slivers with a history of eye injury) should have plain-film radiographs of the orbits to rule out the presence of a metallic fragment before entering the MR environment. There are additional risks involved whenever a parent or guardian fills out the MR screening form because children may not be willing to disclose previous injuries. It is recommended that adolescents are provided additional screening that includes counseling about the hazards associated with the MR environment (101).

BIOMEDICAL IMPLANTS, MATERIALS, AND DEVICES

Patients with biomedical implants, materials, and devices who undergo MR procedures are at risk for dislodgement of the object, induction of electrical currents, excessive heating, and misinterpretation of an imaging artifact as an abnormality.

Aneurysm Clips

There has been much controversy and confusion regarding the amount of ferromagnetism that needs to be present in an aneurysm clip to constitute a hazard for a patient in the MR environment. Presently, the specific guidelines recommended for consideration before exposing individuals with aneurysm clips to the MR environment (52–54) are as follows:

1. Specific information (i.e., manufacturer, type or model, material, lot and serial numbers) about the aneurysm clip must be known, especially with respect to the material used to make the aneurysm clip, so that only patients or individuals with nonferromagnetic or weakly ferromagnetic clips are allowed into the MR environment. This information is provided by the manufacturer in the product label for the clip. The implanting surgeon is responsible for properly communicating this information in the patient's or individual's records.
2. An aneurysm clip that is in its original package and made from phynox, elgiloy, MP35N, titanium alloy, commercially pure titanium, or other material known to be nonferromagnetic or weakly ferromagnetic at 1.5 T or less does not need to be evaluated for ferromagnetism. Aneurysm clips made from nonferromagnetic or weakly ferromagnetic materials in original packages do not require testing of ferromagnetism because the manufacturers ensure the pertinent MR safety aspects of these clips and therefore should be held responsible for the accuracy of the labeling.
3. If the aneurysm clip is not in its original package and properly labeled, it should undergo testing for magnetic field interactions.
4. The radiologist and implanting surgeon should be responsible for evaluating the available information pertaining to the aneurysm clip, verifying its accuracy, obtaining written documentation, and deciding to perform the MR procedure after considering the risk versus benefit aspects for a given patient.

There is additional concern that long-term exposures to strong magnetic fields may grossly magnetize aneurysm clips made from nonferromagnetic material. Five aneurysm clips, made from elgiloy, phynox, titanium alloy, pure titanium, and austenitic stainless steel, were

tested in association with long-term and multiple exposures to the static magnetic fields of a 1.5-T MR system (56). The results of this study indicated a lack of clinically significant changes in the magnetic properties of these devices (56).

Another study evaluating artifacts produced by five different aneurysm clips indicated that the size of the artifacts was directly related to the type of materials used to make the particular clip (57). Titanium alloy and pure titanium produced the smallest artifacts for the aneurysm clips that were evaluated (57).

Cardiovascular Catheters and Accessories

Of the 15 different cardiovascular catheters and accessories selected for evaluation, 5 were determined to have no metallic component (58). These objects were deemed safe for patients undergoing MR procedures and were not included in the ex vivo tests for MR safety. The remaining 10 cardiovascular catheters and accessories evaluated for MR safety at 1.5 T contained metallic materials that are good electrical conductors (58). It is recommended that cardiovascular catheters and accessories with conductive materials should not be present in patients undergoing MR procedures (58). Additionally, the presence of internally or externally placed conductive wires in nonferromagnetic cardiovascular catheters and accessories presents a significant risk of thermal injury. A report indicates that a portion of a thermodilution Swan-Ganz catheter, located outside the patient, melted during an MR procedure (59). Because of such deleterious and unpredictable effects, patients with such devices should not undergo MR procedures (1,75).

Coils, Filters, and Stents

In general, if a patient has a ''passive implant'' (i.e., there is no power associated with the operation of the object) and it is made from a nonferromagnetic material (e.g., elgiloy, phynox, MP35N, titanium, titanium alloy, nitinol, tantalum), the patient may undergo an MR procedure immediately after placement of the implant using an MR system operating at 1.5 T or less (1,60,75). Thus, patients with coils, filters, and stents made from nonferromagnetic materials may undergo MR procedures any time after the placement of such a device (1,75). However, a waiting period of 6–8 weeks after the introduction of a ferromagnetic (or ''weakly'' ferromagnetic) coil, filter, or stent is considered adequate for the implant to become incorporated securely into the vessel wall through tissue growth (1,60,75). Subsequent to this waiting period, patients with these devices can be imaged with MR systems up to and including 1.5 T (60,61,75).

Because of the coiled shape of the Guglielmi detachable coil (GDC) used for endovascular embolization, the potential for excessive heating from induced currents exists. An ex vivo study of this device indicated no magnetic field attraction during MRI. The temperature increase was minimal during ''worst-case'' MRI, and the artifacts involved a mild signal void relative to the size and shape of the GDC (62).

Carotid Artery Vascular Clamps

Although each of the carotid artery vascular clamps tested for ferromagnetism displayed attraction to a 1.5-T static magnetic field, only the Poppen-Blaylock clamp was considered to be contraindicated for patients undergoing MR procedures due to the existence of substantial ferromagnetism (63).

Patent Ductus Arteriosus (PDA), Atrial Septal Defect (ASD), and Ventricular Septal Defect (VSD) Occluders

The metallic PDA, ASD, and VSD occluders tested for magnetic qualities were made from either 304V stainless steel or MP35N. Patients with cardiac occluders made from MP35N (nonferromagnetic) may undergo MR procedures any time after the placement of such a device (64). Patients with occluders made from 304V stainless steel are required to wait approximately 6 weeks after placement to allow for tissue growth to provide an additional retentive force (64).

Heart Valve Prostheses

Most heart valve prostheses evaluated for magnetic field interactions displayed measurable yet relatively minor attraction to static magnetic fields of the MR systems used for testing (65–67). Thus, an MR procedure is not considered to be hazardous for a patient with one of the heart valves that have undergone testing because the attractive forces exerted on these implants are minimal compared with the force exerted by the beating heart (67,68). This includes the Starr-Edwards model Pre-6000 heart valve prosthesis, which was previously suggested to be a potential hazard for a patient undergoing an MR procedure (1,75,79). If there is a question of a dehisced valve, caution is recommended on exposure to the MR environment.

Vascular Access Ports and Catheters

Although three of the vascular access ports and catheters evaluated showed measurable attraction to the static magnetic field of the MR system, the forces were minor relative to the in vivo application of these implants (69,70). Therefore, it is considered safe to perform MR procedures in patients with these specific implants.

ELECTRICALLY, MAGNETICALLY, OR MECHANICALLY ACTIVATED IMPLANTS AND DEVICES

Patients with internal cardiac pacemakers, implantable cardioverter defibrillators (ICD), cochlear implants, neurostimulators, bone growth stimulators, implantable electronic drug infusion pumps, and other similar devices should not undergo MR procedures, unless testing of these devices has indicated that they are ''MR safe.''

Cardiac Pacemakers

The presence of a cardiac pacemaker is considered a strict contraindication for patients undergoing an MR procedure using conventional MR systems (45). There have been at least 6 fatalities among the several patients (at least 12) with pacemakers who have been placed in MR systems. However, the causes of death in these cases are unknown (1,75). Conversely, there have been cases whereby patients with pacemakers have safely undergone MRI procedures. Notably, patients with cardiac pacemakers who are pacemaker dependent should never undergo MRI procedures using conventional MR systems.

Presently, reed-switch closure is not thought to be the causative factor for adverse patient outcomes (1,75). Reed-switch closure simply places the pacemaker into an asynchronous mode, causing a predetermined fixed rate to take over during the period that the reed switch is activated (1,75). Notably, induction of voltages and currents within the pacemaker–lead–myocardial loop can result in cardiac arrhythmias that yield cardiac outputs incompatible with sustaining life. Several cardiac pacemaker studies have shown human subjects to become tachyarrhythmic and/or hypotensive during MR studies. This mechanism seems to be the cause of death in some of the cardiac pacemaker patients that underwent MR procedures (71).

Heating of the pacemaker/pacing leads during MRI can result in thermal injury to the myocardium and endocardium. A recent investigation reported that it was possible for electrodes exposed to MR imaging under certain conditions to have temperature increases of up to 63.1°C within 90 sec of scanning (72).

Implantable Cardioverter Defibrillators

Deactivation of ICD can be accomplished by holding a magnet over the device for approximately 30 sec (73). Magnetic fields of MR systems would have a similar effect on ICDs, and therefore patients with these devices should avoid exposure to the MR environment (50, 51,73).

Retained Cardiac Pacing Wires

A study by Hartnell et al. (74) reported that patients with retained temporary epicardial pacing wires, cut short at the skin (i.e., after they were no longer used postsurgically), did not experience any changes in baseline ECG rhythms or experience any symptoms during MR procedures.

The investigation by Hartnell et al. is of particular importance because the presence of retained pacing wires was previously considered to be a relative contraindication for MR procedures due to the theoretic risk of inducing current that, in turn, could produce arrhythmias in patients. Notably, the study by Hartnell et al. used 1.0- and 1.5-T MR systems operating with conventional pulse sequences. Therefore, it would be prudent to use similar MR techniques and parameters as Hartnell et al. for patients with temporary pacing wires until additional investigations are conducted.

Temporary Cardiac Pacing Wires

An investigation was conducted to assess the MR safety of two different cardiac pacing wires (F. Shellock, unpublished observations, 1999; 75): Temporary Cardiac Pacing Wire, TPW-62, 0 (3.5 metric), (316L stainless steel), Ethicon, Inc., Somerville, NJ and Temporary Cardiac Pacing Wire With Wave, TPW92, 2-0 (3.0 metric), (316L stainless steel), Ethicon, Inc. Based on the results of this investigation, specific recommended guidelines for performing an MR procedure in a patient with the temporary cardiac pacing wires that have been tested were developed:

1. The temporary cardiac pacing wires must be disconnected from the pulse generator before the MR procedure (i.e., the patient cannot be paced during the MR procedure). The pulse generator must not be placed in the MRI environment.
2. The end of each temporary cardiac pacing wire

(i.e., the straight leads that connect to the pulse generator) should be taped to insulate it. The ends of the temporary cardiac pacing wires should then be securely attached to the patient using adhesive or other type of tape.

3. The temporary cardiac pacing wires should be placed on the patient in a ''straight line'' configuration, without any loops and fixed in this position using tape or other means.
4. Static magnetic field of the MR system and pulse sequences: MRI should only be performed using MR systems with static magnetic fields of 1.5 T or less and conventional techniques. Standard spin echo, fast spin echo, and gradient echo pulse sequences may be used. Pulse sequences (e.g., echo planar techniques) or conditions that produce exposures to high levels of RF energy (i.e., exceeding a whole body–averaged specific absorption rate of 1.1 W/kg) or exposure to gradient fields that exceed 20 T/sec, or any other unconventional MRI technique, should be avoided.
5. Gradient magnetic fields of the MR system: Pulse sequences (e.g., echo planar imaging techniques or other rapid imaging pulse sequences), gradient coils or other techniques and procedures that exceed a gradient magnetic field of 20 T/sec must not be used for MRI procedures. The use of unconventional or nonstandard MRI techniques must be avoided.
6. RF fields of the MR system: MRI procedures must not exceed exposures to RF fields greater than a whole body–averaged SAR of 1.1 W/kg. The use of unconventional or nonstandard MRI techniques must be avoided.
7. Similar to the performance of other MR procedures, the patient should be continuously observed during the MR procedure and instructed to report any unusual sensations to the MR system operator. If any unusual sensation occurs, the MR procedure must be discontinued.
8. Qualified personnel (advanced cardiac life-support certified healthcare worker or physician) should be present to respond immediately to any problem whenever a patient with a temporary pacing wire undergoes an MRI procedure.

Bone Fusion Stimulator

The implantable spinal fusion or bone fusion stimulator (Electro-Biology, Inc., Parsippany, NJ) is designed for use as an adjunct therapy to a spinal fusion procedure. The use of this implant provides a faster consolidation of the bone grafts, leading to higher fusion rates and improved surgical outcomes, along with a reduced need for orthopedic instrumentation.

Recent studies using excessively high electromagnetic fields under highly specific experimental conditions and modeling scenarios for the lumbar/torso area (i.e., high-field-strength MR system, excessive exposures to RF fields, excessive exposures to gradient magnetic fields, etc.) have demonstrated that the implantable bone fusion stimulator will not present a hazard to a patient undergoing MRI with respect to movement, heating, or induced electric fields during the use of conventional MR techniques (76,77). Additionally, there was no evidence of malfunction of the implantable bone fusion stimulator based on in vitro and in vivo experimental findings (76). In general, it is believed that the implantable bone fusion stimulator is safe for patients undergoing MR procedures following specific guidelines. Recommended guidelines for conducting an MR examination in a patient with the implantable bone fusion stimulator are indicated in the following list:

1. The cathodes of the implantable bone fusion stimulator should be positioned a minimum of 1 cm from nerve roots to reduce the possibility of nerve excitation.
2. Plain-film radiographs should be obtained before MRI to verify that there are no broken leads present for the implantable spinal fusion stimulator. If this cannot be reliably determined, then the potential risks and benefits to the patient requiring MRI must be carefully assessed in consideration of the possibility for excessive heating to develop in the leads.
3. MRI should be performed using MR systems with static magnetic fields of 1.5 T or less and conventional techniques. Pulse sequences that produce exposures to high levels of RF energy (i.e., exceeding a whole body–averaged specific absorption rate of 1.0 W/kg) or exposure to gradient fields that exceed 20 T/sec should be avoided.
4. Patients should be continuously observed during MRI and instructed to report any unusual sensations, including any feelings of warming, burning, or neuromuscular excitation or stimulation.
5. The implantable bone fusion stimulator should be placed as far as possible from the spinal canal and bone graft because this will decrease the likelihood that artifacts will affect the area of interest on MR images.

Neurostimulators

The electromagnetic fields used for MR procedures may produce problems with the operation of neurostimulators, resulting in pain or discomfort to the patient (78). In extreme cases, damage to the nerve fibers at the site of the implanted electrodes of the neurostimulator may also occur (78). The present policy regarding a patient with a neurostimulator is that the individual should not undergo an MR procedure unless testing has been conducted to define parameters and guidelines for the safe use of such a device (23,50,51,79). One neurostimulator, the NeuroCybernetic Prosthesis NCP Pulse Generator (model 100, Cyberonics, Houston, TX), has received MR safe labeling from the FDA, allowing MR procedures to be conducted on a patient with this device on the condition that strict guidelines are followed (see information posted on *www.MRIsafety.com*).

MR PROCEDURES AND THE POSTOPERATIVE PATIENT

Unfortunately, there is great confusion regarding the issue of performing an MR procedure during the postoperative period in a patient with a metallic implant, material, or device. In general, if the metallic object is a ''passive implant'' (i.e., there is no power associated with the operation of the device) and made from a nonferromagnetic material (e.g., elgiloy, phynox, MP35N, titanium, titanium alloy, nitinol, tantalum), the patient with the object may undergo an MR procedure immediately after placement of the object using an MR system operating at 1.5 T or less (1,60,64,75).

For an object that is ''weakly'' magnetic, it is typically necessary to wait a period of 6–8 weeks before performing an MR procedure (1,60,64,75). In this case, ''retentive'' or counterforces provided by tissue in growth, scarring, or granulation serve to prevent the object from presenting a hazard to the patient or individual in the MRI environment.

For example, certain types of intravascular coils, filters, stents, and cardiac occluders that are weakly ferromagnetic typically become firmly incorporated into the tissue 6 to 8 weeks after placement (1,60,64,75). Therefore, it is unlikely that these objects will be moved or dislodged by magnetic field interactions associated with MR systems operating at 1.5 T or less.

Notably, there has never been a report of an injury to a patient or individual in association with an MRI procedure and one of the coils, stents, filters, cardiac occluders, and heart valve prostheses for the devices that have undergone testing. Obviously, if there is any concern regarding the integrity of the tissue with respect to its ability to retain the object in place during an MR procedure or during exposure to the MRI environment, the patient or individual should not be exposed to the MRI environment.

EXTREMITY MR SYSTEM

MRI using the 0.2-T extremity MR system (Artoscan, Esaote, Milan, Italy and Lunar Corporation, Madison, WI) has been demonstrated to provide a sensitive, accurate, and reliable assessment of various forms of musculoskeletal pathology (102,103). The patient is positioned within this system such that only the patient's extremity is predominantly exposed to the MR-related electromagnetic fields when a procedure is performed.

Considering the unique design features of the extremity MR system, it was suggested that it might be possible to safely image patients with aneurysm clips, even if they were made from ferromagnetic material. A study performed to assess the magnetic field interaction of 22 different types of aneurysm clips exposed to the 0.2-T extremity MR system showed that none of the clips tested (nonferromagnetic, weakly ferromagnetic, or ferromagnetic) displayed substantial magnetic field interaction (80). Therefore, it is considered safe to perform MRI in patients with the specific aneurysm clips tested using a 0.2-T extremity MR system (80).

Because the patient's thorax (i.e., the area where pacemakers or ICDs are typically placed) remains outside of the MR system, it is not possible for the MR system's gradient or RF magnetic fields to induce currents in these devices. Ex vivo experiments conducted on seven different pacemakers and seven different ICDs (Medtronic, Inc., Minneapolis, MN) indicated that magnetic field attraction did not present problems for these devices (81).

The activation of the pacemakers and the ICDs did not substantially affect image quality during MRI (81). Importantly, the operation of the extremity MR system produced no alterations in the function of the cardiac pacemakers and ICDs (81). Therefore, it should be safe for patients with the specific cardiac pacemakers or ICDs evaluated to undergo imaging using the 0.2-T extremity MR system (81).

In 1998, a new type of extremity MR system was developed to conduct MR examinations of the shoulders and limbs, and in 2000 a 1.0-T extremity MR system was developed. Presently, these new systems should not be

used in patients with ferromagnetic aneurysm clips, cardiac pacemakers, or ICDs. Further studies are necessary to determine if these particular extremity MR systems may be used in patients with ferromagnetic implants or other typically contraindicated devices.

PHYSIOLOGIC MONITORING DURING MR PROCEDURES

Monitoring the patient's vital signs during an MR procedure may be indicated due to an underlying health problem or whenever the patient is unable to alert the MR healthcare provider regarding pain, respiratory problems, cardiac distress, or other difficulty that might arise during the examination (82). With the advent of MR-guided surgery, there is an increased need to monitor patients in the MR environment. Furthermore, MR facilities that use echo planar imaging or static magnetic fields greater than 2 T may require continuous physiologic monitoring of patients due to the potential risks associated with these devices (1,75).

Several hazards are associated with the performance of patient monitoring during MR examination. Physiologic monitors that contain ferromagnetic components pose a serious ''missile'' hazard (83–86). RF fields from the MR system can affect the operation of the monitor (1,75). The monitor may emit spurious noise that distorts the MR image (1,75). Electrical currents generated in the conductive material present in the monitors may be of sufficient magnitude to cause thermal injury to the patient (83,87–90). Numerous first-, second-, and third-degree burns, which occurred in association with MR procedures, have been directly attributed to the use of ECG lead wires, plethysmographic gating systems, hard-wire pulse oximeters, and other types of monitors that require the use of wires or cables made from conducting materials (83,87–90).

Fortunately, various monitors and other patient-support devices have been developed or specially modified to perform during MR procedures using MR systems with static magnetic fields up to 1.5 T (1,75).

WEBSITE FOR MRI SAFETY*

A new website, *www.MRIsafety.com*, was recently developed to provide crucial and timely information to healthcare providers and patients seeking answers to questions on MRI safety topics and issues. In addition, the latest information is provided for screening patients with implants, materials, and medical devices. The key features of *www.MRIsafety.com* include the following:

1. *The List*. A searchable database that contains over 900 implants and other objects tested for MR safety.
2. *Safety Information*. Useful information that pertains to patient care and management in the MRI environment.
3. *Summary*. A presentation of over 100 peer-reviewed articles on MRI bioeffects and safety.
4. *Screening Form*. A form for pre-MRI screening with software to download by imaging facilities.

* An unrestricted educational grant was provided by Bracco Diagnostics, Inc. (Princeton, NJ) to create www.MRIsafety.com. This website was developed and is maintained by Frank G. Shellock, PhD. Manufacturer information for products cited throughout this article may be found at *www.MRIsafety.com.*

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Received March 2, 2000
Accepted October 25, 2000